PCT/EP2002/010353

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 24157PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP2002/010353	International filing date (*day/month/year*) 16 September 2002 (16.09.2002)	Priority date (*day/month/year*)
International Patent Classification (IPC) or national classification and IPC A61M 15/00		
Applicant SCHUCKMANN, Alfred von		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 8 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
18 February 2004 (18.02.2004)	19 January 2005 (19.01.2005)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP2002/010353

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:

pages 3-16, as originally filed
pages 2, 2A (with the fax of 12.01.05), filed with the demand
pages 1, filed with the letter of 01 October 2004 (01.10.2004)

☒ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages 1-27, filed with the letter of 01 October 2004 (01.10.2004)

☒ the drawings:

pages 1/5-5/5, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP 02/10353

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-27	YES
	Claims		NO
Inventive step (IS)	Claims	7, 9-11, 14-26	YES
	Claims	1-6, 8, 12, 13, 27	NO
Industrial applicability (IA)	Claims	1-27	YES
	Claims		NO

2. Citations and explanations

1 This report refers to the following documents:
D1: WO-A-01/21238 (2001-03-29)
D2: US-A-5 239 992 (1993-08-31)
D4: US-A-5 429 122 (1995-07-04).

2 The present application does not meet the requirements of PCT Article 33(1) because the subject matter of claim 1 does not involve an inventive step within the meaning of PCT Article 33(3).

2.1 Document **D1** is considered to be the prior art closest to the subject matter of claim 1. It discloses (the references in parentheses relate to this document) an inhaler ("powder inhaler", see fig. 1) for substances in powdered form, in particular medicinal substances ("powdered medicament"), with a suction air channel (11) leading to a mouthpiece (the "outer casing 2" defines a mouthpiece), a supply chamber (1) for the substance and a dosing chamber (5) that is moved linearly by a rod (3) to meter a specific amount of substance from the supply chamber (1) into the

region of a point of delivery (see fig. 3) to the suction air stream, characterized in that the mouthpiece (2) formed at the head end (**either end can be considered a head end**) of the inhaler, which is substantially rotationally symmetrical to the central longitudinal axis (**the inhaler's central longitudinal axis defined by the rod 3**) (the inhaler described in D1 is designed as **substantially** rotationally symmetrical to the central longitudinal axis defined by the rod 3), has an air inlet (12) used to form a central suction air stream, and that the dosing chamber (5) takes the form of a transverse bore running substantially perpendicular to the central longitudinal axis (**the inhaler's central longitudinal axis defined by the rod 3**) and, situated in the discharge position (see fig. 3) in the effective area of the central suction air stream, is discharged by a component of the suction air stream in the direction of the dosing chamber's (5) extension (**the dosing chamber 5 in D1 is discharged by the entire suction air stream**).

The subject matter of claim 1 differs, then, from the known inhaler in that the mouthpiece formed at the head end has **air inlets.**

This distinguishing feature does not solve any technical problem, and hence the subject matter of claim 1 is merely one of a number of obvious alternatives from which a person skilled in the art would choose according to the circumstances without thereby being inventive (PCT Article 33(3)).

2.2 The same argument applies analogously to independent claim 1 in relation to the disclosure of document

D2. The subject matter of claim 1 therefore does not involve an inventive step (PCT Article 33(3)).

D2 discloses (the references in parentheses relate to this document) an inhaler (see fig. 1) for substances (8) in powdered form, in particular medicinal substances, with a suction air channel leading to a mouthpiece, a supply chamber (7) for the substance (8) and a dosing chamber (3) that is moved linearly by a rod (2b) to meter a specific amount of substance from the supply chamber (7) into the region of a point of delivery (see fig. 1) to the suction air stream, characterized in that the mouthpiece (4) formed at the head end of the inhaler, which is substantially rotationally symmetrical to the central longitudinal axis (**the inhaler's central longitudinal axis defined by the rod 2b**) (the inhaler described in D2 is designed as **substantially** rotationally symmetrical to the central longitudinal axis defined by the rod 2b), has an air inlet (12) used to form a central suction air stream, and that the dosing chamber takes the form of a transverse bore running substantially perpendicular to the central longitudinal axis and, situated in the discharge position in the effective area of the central suction air stream, is discharged by a component of the suction air stream in the direction of the dosing chamber's (3) extension (**the dosing chamber 3 in D2 is discharged by the entire suction air stream**).

2.3 Document **D4** discloses (the references in parentheses relate to this document) an inhaler (see fig. 1, 2) for substances in powder form, in particular medicinal substances, with a suction air channel

leading to a mouthpiece (7), a supply chamber (3) for the substance and a dosing chamber ("recess" between 13 and 14) that is moved linearly by a rod (11) to meter a specific amount of substance from the supply chamber (3) into the region of a point of delivery (see fig. 2) to the suction air stream, characterized in that the mouthpiece (7) formed at the head end of the inhaler, which is substantially rotationally symmetrical to the central longitudinal axis (**the inhaler's central longitudinal axis defined by the rod (11)**) has air inlets (18, 19) used to form a central suction air stream, and that the dosing chamber (recess between 13 and 14), situated in the discharge position (fig. 2) in the effective area of the central suction air stream, is discharged by a component of the suction air stream in the direction of extension of the dosing chamber (**the dosing chamber in D4 is discharged by a component of the suction air stream in the direction of extension of the dosing chamber OR by the entire suction air stream**).

The subject matter of claim 1 differs, then, from the known inhaler in that the dosing chamber takes the form of a transverse bore running substantially perpendicular to the central longitudinal axis. This feature represents merely one of a number of obvious alternatives from which a person skilled in the art would choose according to the circumstances without thereby being inventive - see documents D1 and/or D2. Consequently, the subject matter of claim 1 does not involve an inventive step (PCT Article 33(3)).

3 Dependent claims 2-6, 8, 12, 13 and 27 do not contain any features which in combination with the

features of any claim to which they refer back meet the PCT requirements for inventive step.

3.1 The additional features of claim 2 are already known from document D2. The subject matter of claim 2 does not, therefore, involve an inventive step (PCT Article 33(3)).
- **claim 2:** closure cap = "removable closing cap 8"

3.2 The additional features of claims 3-6 and 8 are already known from document D2. The subject matter of these claims does not, therefore, involve an inventive step (PCT Article 33(3)).
- **claims 4-6 and 8:** air passages = "passages 13"

3.3 Dependent claims 12, 13 and 27 concern minor structural changes that fall within the compass of what a person skilled in the art routinely does on the basis of familiar considerations, especially as the advantages achieved thereby are readily foreseeable. Consequently, the subject matter of these claims also is not based on an inventive step (PCT Article 33(3)).

4 The combination of features in dependent claim 7 is neither disclosed nor suggested by the relevant prior art. The reasons therefor are as follows:

Document D2, which is taken as the closest prior art, discloses an inhaler from which the subject of claim 7 differs in that the air passages are formed on a pot-shaped swivel that guides the rod and are flow-connected to air inlets in the wall of the mouthpiece.
The subject of claim 7 is thus novel (PCT Article

33(2)).

The air passages in question are so placed on the wall of the inhaler that they cannot be stopped by the lips of the user, nor by the hand grasping the body of the inhaler. Moreover, the formation of multiple, spaced air passages minimizes the danger of contact. This arrangement of air passages to the air inlets situated closer to the mouthpiece also ensures a better distribution of the powdered substance to the suction air stream.

The solution to this problem as proposed in claim 7 of the present application is not described or suggested either in D2 or in any of the other search report citations. Consequently, the subject matter of claim 7 involves an inventive step (PCT Article 33(3)):

4.1 Claims 9-11 and 14-26 are dependent on claim 7 and thus also meet the PCT requirements for novelty and inventive step.

5 The subject matter of claim 1-27 has industrial applicability in the field of medicine (PCT Article 33(4)).

Certain observations on the international application

6 Claims 11, 13 and 19 are unclear (PCT Article 6).

6.1 The blades (33) in claim 11 were introduced in claim 10, and hence claim 11 cannot refer back to claims 1 to 9.

6.2 The closure cap (4) in claim 13 was introduced in claim 2, and hence claim 13 cannot refer back to claim 1.

6.3 The flanks (50) in claim 19 were introduced in claim 18, and hence claim 19 cannot refer back to claims 14 to 17.